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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,280	07/14/2003	Steven C. Quay	PT00105 CON	7740

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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,280	QUAY, STEVEN C.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 34-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 34-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/14/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims priority to multiple parent applications. It is noted that the concept of perfluorohexane in a gaseous state was first introduced in claims 26 – 27 of related US patent 5,595,723, and as such the priority date for this terminology was considered by the examiner to be the filing date of the '723 patent application: 11/08/1993.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 36 and 37 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10 and 11 of prior U.S. Patent No. 5,558,854. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34 – 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,569,404; 5,707,606; 5,595,723; 5,558,854; 5,558,853; and 5,409,688. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to the use of specific perfluorocarbon gases, including perfluorohexane, which would be encompassed within the broader claims of the cited patents. Moreover, the cited patents are all directed to ultrasound contrast agents, accordingly, the scope of the pending claims overlap with those of the patented claims, and thus they are obvious variants of the patented claims.

Claims 34 – 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 11/106,350. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the use of ultrasound contrast agents comprising the same perfluorocarbons, specifically perfluorohexane, as the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is drawn to perfluorocarbon compounds with *at least six carbon atoms* with a vapor pressure above about 20 Torr at ambient temperature or a boiling point below about 100 °C. While there are several specific perfluorocarbons that are recited in the specification, disclosure of a species (i.e. a specific perfluorocarbon) does not provide enablement for a genus (i.e. any perfluorocarbon chemical with at least six carbon atoms and additional limitations).

Claims 34 – 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the disclosure lacks sufficient written description for methods for contrast media comprising gaseous perfluorohexane.

The only mention of using perfluorohexane in a contrast media is described in Example 18, page 28 – 30 of the specification. This example is directed to a liquid-liquid dispersion, and not a dispersion containing gas. For example, the specification clearly refers to the use of perfluorohexane and perfluorooctane in the liquid state whereby "the high vapor pressure liquids perfluorohexane and perfluorooctane, which have vapor pressures at ambient temperature above 20 Torr, provided some contrast when compared to agitated saline or perfluorodecalin, which has a vapor pressure at ambient temperature below 20 Torr" (Example 18).

The instant claims are product claims directed to gaseous perfluorohexane. The product to be administered is not in gaseous form. Accordingly, Applicant has failed to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34 – 36 and 39 - 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger (US 5,205,290).

Unger discloses contrast imaging agents comprising volatile liquids useful in heating expansion selected from the group of perfluorocarbons such as those having between 1 and about 9 carbon atoms and about 4 to about 20 fluorine atoms, especially C_4F_{10} (perfluorobutane) (column 4, lines 25 – 29). The term perfluorocarbon, as generally used in the art, refers to compounds that contain only fluorine and carbon, and as such compounds ranging from $CF_4 – C_9F_{20}$ would be envisaged, and therefore Unger teaches compounds having perfluorocarbon moieties with at least C_6. The contrast agents of Unger comprise gaseous microspheres having expanding compounds within the microspheres of the contrast agents (abstract and column 4, lines 9 – 58). Unger's contrast agents are heated prior to use to allow expansion of the internal gas (see column 4, lines 49 – 55). Unger discloses the use of liquids which undergo liquid / gas transition (see column 4, lines 59 – 61). Unger's compositions are used for in vivo administration, and are therefore biocompatible. Furthermore, the compositions may comprise a perfluorocarbon surfactant (column 7, line 50), which meets the limitations of claims 39 – 41.

It is noted that the compositions taught by Unger are utilized in CT imaging, rather than ultrasound imaging. However, a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 34 – 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Schutt *et al.*, (08/099,951; now US 5,639,443).

Schutt discloses microbubbles from an aqueous medium for use as ultrasound contrast agents which comprise perfluorohexane, and which comprise also contain 2% Pluronic F-68 as a surfactant (column 19, Example 1 and abstract). Accordingly Schutt anticipates claims 34 – 41.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 5,147,631) in view of Unger (US 5,205,290).

Glajch teaches gas containing ultrasonic imaging contrast agents (abstract). Glajch further teaches that the gas is entrapped in particles can include light gases such as CF_4 (perfluoromethane) and C_2F_6 (perfluoroethane) (column 7, lines 37 – 52). Glajch narrows the scope of suitable perfluorocarbons in ultrasound imaging to those having lower molecular weight (column 13, lines 10 – 14). However, Glajch fails to utilize the specific perfluorohexane gas of the instant claims.

Unger teaches contrast agents comprising gaseous microspheres (abstract). Unger also teaches the use of volatile liquids having low boiling points within said microspheres to allow expansion of the microspheres (column 4, lines 9 – 58). Unger specifically teaches the use of perfluorocarbons such as those having between 1 and 9 carbon atoms and between 4 and 20 fluorine atoms (i.e. $CF_4 - C_9F_{20}$). The compositions may also comprise a fluorine-containing surfactant (column 7, line 50). However, Unger fails to utilize the microspheres comprising perfluorocarbon gas for ultrasound imaging.

The teachings of Glajch and Unger are analogous because they both teach the use of gaseous perfluorocarbons in the filed of correlative imaging. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Glajch regarding the use or gaseous perfluorocarbons for ultrasonic imaging with the teachings of Unger, whereby larger perfluorocarbons were shown to be useful contrast agents. Accordingly, absent of showing unexpected results, one of ordinary skill in the art would have had a reasonable expectation of observing similar properties as perfluoromethane or perfluoroethane, by using compounds within the range of those taught by Unger, which includes perfluorohexane, for obtaining ultrasound images.

Protest Under 37 CFR 1.291

A protest against issuance of a patent based upon this application has been filed under 37 CFR 1.291(a) on August 23, 2002. The Protest was based upon the subject matter of the interference No. 104,428, which involved an application of Schutt *et al.*

assigned to Alliance Pharmaceutical Corp and an application of Quay, Serial No 08/380,085 which issued as US Patent 5,558, 854, and which teaches substantially similar subject matter to that of the instant application. The count of the interference was based on identical claims of both parties, reading "contrast media for ultrasound imaging comprising gaseous perfluorohexane." The Board of Patent Appeals and Interferences held in part that Quay's application Serial No 09/380,085 which issued as US Patent 5,558,854 contained no written description of any ultrasound contrast compositions comprising gaseous perfluorohexane.

The claims of the instant application are directed to ultrasonic contrast media comprising gaseous perfluorohexane and the Protest effects on the merits of this Application. Any comments or reply applicant desires to file in relation to the Protest must be filed in response to this Office Action.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER